

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. **(Currently Amended)** An anticonvulsant pharmaceutical composition for nasal administration comprising ~~having a binding affinity for at least one receptor site selected from the group consisting of Gamma-Amino-Butyric Acid (GABA) A-agonist site, Glutamate-alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) site, Glutamate-Kainate site, Glutamate-N-methyl-D-aspartic acid (NMDA) agonistic site, Glutamate-N-methyl-D-aspartic acid (NMDA)-glycine (strychnine insensitive) site and Sodium channel (site 2), consisting essentially of:~~

- i. an aqueous, alcoholic, or hydroalcoholic extract comprising a mixture of saponins derived from ~~of a pericarp of the fruit of~~ *Sapindus (S.) trifoliatus*, the saponins present in the extract calculated as ~~comprising of total saponins expressed as~~ hederagenin from 0.001 to 1.0 % w/v, and
- ii. at least one pharmaceutically acceptable additive,

the composition devoid of extract from *Emblica officinalis*.

2. **(Currently Amended)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, ~~wherein the~~ saponins present in the extract calculated as ~~comprises total saponins expressed as~~ hederagenin in an amount from 0.004% to 0.08 % w/v.

3. **(Original)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, wherein the said extract is in the form of a lyophilized powder or an aqueous solution.

4. **(Original)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, being suitable for prophylactic treatment of migraine, mediated through its anticonvulsant activity.

5. **(Previously presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the least one pharmaceutically acceptable additive is selected from the group consisting of at least one preservative agent, at least one agent for adjusting the tonicity, at least one agent for adjusting viscosity, and at least one agent for adjusting pH.

6. **(Original)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said agent for adjusting the tonicity, is sodium chloride.

7. **(Withdrawn)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said agent for adjusting the viscosity is selected from the group consisting of xanthan gum, carboxymethyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol and carbomers.

8. **(Withdrawn)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said agent for adjusting the pH is selected from the group consisting of citric acid, sodium citrate, potassium dihydrogen phosphate, acetic acid, sodium acetate and ammonium acetate.

9. **(Withdrawn)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said preservative agent is selected from the group consisting of chlorbutanol, phenyl ethyl alcohol and parabens.

10. **(Previously presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the pH, is in the range of between 4.5-6.5.

11. **(Previously presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the said composition is in the form selected from the group consisting of nasal drops, nasal sprays, nasal powders, semisolid nasal preparations, nasal washes, and nasal sticks.

12. **(Withdrawn)** A process for preparation of an extract containing 4 to 8% w/w of hederagenin, comprising the steps of:

- a. extraction of the pericarp of the fruit of *S.trifoliatus* with water or an alcohol or a mixture thereof at ambient to boiling temperature for 0.5 to 24 hours,
- b. lyophilization of the aqueous, alcoholic or aqueous alcoholic extract containing a mixture of saponins to give a lyophilized powder, containing a mixture of saponins, and
- c. reconstitution of the lyophilized extract in water to achieve a concentration of hederagenin between 0.001 to 1.0 (% w/v).

13. **(Withdrawn)** A process according to claim 12, wherein the alcohol is selected from a C<sub>1-4</sub> alcohol.

14. **(Withdrawn)** A process according to claim 12 wherein the C<sub>1-4</sub> alcohol is selected from the group consisting of methanol, ethanol, n-propanol, iso-propanol, n-butanol, iso-butanol and tert- butanol.

15. **(Withdrawn)** A process for preparation of an anticonvulsant pharmaceutical composition comprising:

- i. adding lyophilized aqueous extract of *Sapindus (S.)trifoliatus* as formed in accordance with the process of claim 12 to a mixture of Chlorobutanol and Phenylethyl alcohol in water and sodium chloride, to get a uniform dispersion,
- ii. filtering;
- iii. mixing above dispersion with dispersion of Xanthan gum in purified water; and
- iv. adjusting the pH between 4.5-6.5.

16. **(Withdrawn)** A composition according to claim 1 which exhibits *in vitro* receptor binding affinity towards a receptor selected from the group consisting of Gamma-Amino Butyric

Acid (GABA)-A agonistic site, Glutamate-*N*-methyl-D-aspartic acid (NMDA) agonistic site, Glutamate-*N*-methyl-D-aspartic acid (NMDA) Glycine (strychnine insensitive) site and sodium channel (site 2) which have mediatory role in anticonvulsant effect.

17. **(Withdrawn)** A composition according to claim 1 wherein the *in vivo* anticonvulsant activity in rat in accordance with a Maximal Electroshock Seizure model is exhibited by nasal administration.

18. **(Withdrawn)** A composition according to claim 17 wherein the anticonvulsant activity exhibited in the Maximal Electroshock Seizure model of rat by intra nasal route of administration is without loss of motor co-ordination in rat in the effective dose range.

19. **(Withdrawn)** A method of prophylactic treatment of migraine through anticonvulsant activity of the pharmaceutical composition according to claim 1 by its administration through intranasal route.

20. **(Withdrawn)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the composition comprises pharmaceutically acceptable additives comprising a preservative agent, an agent for adjusting tonicity, an agent for adjusting viscosity, and an agent for adjusting pH.

21. **(Previously Presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, said composition having a binding affinity for the receptor site Glutamate AMPA site.

22. **(Previously Presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, said composition having a binding affinity for the receptor site Glutamate-Kainate site.

23. **(Previously Presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, said composition having a binding affinity for the receptor site NMDA glycine (strychnine insensitive) site.

24. **(Previously Presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, said composition having a binding affinity for the receptor site Sodium channel (site 2).

25. **(Previously Presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, said composition having a binding affinity for the receptor site Glutamate (NMDA) agonistic site.

26. **(Previously Presented)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, said composition having a binding affinity for the receptor site Gamma-Amino Butyric Acid (GABA)-A agonist site.